

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant(s): Glynn Thomas Faircloth et al.

Serial No.: 10/531,533

Group Art Unit: 1654

Filed: April 25, 2006

Examiner: Maury Audet

For: New Antitumoral Compounds

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**

Sir:

This Information Disclosure Statement is filed in accordance with 37 C.F.R. §§1.56, 1.97 and 1.98. The items listed on Form PTO-1449, a copy of which is enclosed, are made of record to assist the Patent and Trademark Office in its examination of this application. The Examiner is respectfully requested to fully consider the items and to independently ascertain their teaching.

1.  For each of the following items listed on the enclosed copy of Form PTO-1449 that is not in the English language, an English language translation of that item or a portion thereof or a concise explanation of the relevance of that item is enclosed;
2.  For each of the following items listed on the enclosed copy of Form PTO-1449 that is not in the English language, a concise explanation of the relevance of that item is incorporated in the specification of the above-identified application.
3.  Any copy of the items listed on the enclosed copy of Form PTO-1449 that is not enclosed with this Information Disclosure Statement was previously cited by or submitted to the Patent and Trademark Office in

**U.S. Patent 6,274,551: cited references A17 and A18 from Form PTO 1449b.**

4.  No fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with:
  - 37 C.F.R. §1.97(b)(1), within three months of the filing date of a national application other than a CPA; or
  - 37 C.F.R. §1.97(b)(2), within three months of the date of entry into the national stage as set forth in §1.491 in an international application; or
  - 37 C.F.R. §1.97(b)(3), before the mailing date of a first Office action on the merits; or

37 C.F.R. §1.97(b)(4) before the mailing date of a first office action after the filing of an RCE under §1.114.

5.  No fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(c), after the period specified in paragraph 4 above but before the mailing date of a final action or a Notice of Allowance (where there has been no prior final action), and is accompanied by one of the certifications pursuant to 37 C.F.R. §1.97(e) set forth in paragraph 9 below.

6.  A fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(c), after the period specified in paragraph 4 above but before the mailing date of a final action or a notice of allowance (where there has been no prior final action):  
 A check in the amount of \$180.00 is enclosed in payment of the fee.  
 Charge the fee to Deposit Account No. 50-3732, Order No. 13566.105012.

7.  A fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(d), after the mailing date of a final action or a notice of allowance, whichever comes first, but before payment of the issue fee, and is accompanied by:  
a. one of the certifications pursuant to 37 C.F.R. §1.97(e) set forth in paragraph 9 below; and  
b. the fee due under 37 C.F.R. §1.17(p) which is paid as set forth in paragraph 11 below.

8.  This Information Disclosure Statement is being filed in compliance with:  
a.  37 C.F.R. §1.313(b)(3) or §1.313(c)(1), after the issue fee has been paid and information cited in this Information Disclosure Statement may render at least one claim unpatentable and is accompanied by the attached Petition To Withdraw Application From Issue and fee pursuant to 37 C.F.R. §1.17(h);  
b.  37 C.F.R. §1.313(c)(2) or §1.313(c)(3), after the issue fee has been paid and information cited in this Information Disclosure Statement is to be considered in a Request for Continued Examination (RCE) or a Continuation application upon abandonment of the instant application and is accompanied by the attached Petition To Withdraw Application From Issue and fee pursuant to 37 C.F.R. §1.17(h).  
c.  The fee due under 37 C.F.R. §§1.17(h) is paid as set forth in paragraph 11 below.

9.  I hereby certify that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.  
 I hereby certify that no item of information in the Information Disclosure Statement filed herewith was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in §1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

10.  This document is accompanied by  a Search Report  Communication which was cited in a corresponding  PCT or  Foreign counterpart application.

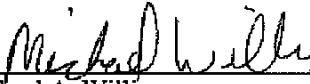
11.  A check in the amount of \$ \_\_\_\_\_ is enclosed in payment of the fees due under 37 C.F.R. §§1.17(h) and 1.17(p).  
 Charge the fees due under 37 C.F.R. §§1.17(h) and 1.17(p) to Deposit Account No. 50-3732, Order No. 13566.105012.

The Commissioner is hereby authorized to charge any additional fees which may be required for this Information Disclosure Statement, or credit any overpayment to Deposit Account No. 50-3732, Order No. 13566.105012.

Respectfully submitted,  
KING & SPALDING LLP

Dated: April 2, 2007

By:

  
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## RELATED CASE STATEMENT

SERIAL NO.	FILING DATE	ATTY. DOCKET NO.
10/531,533	April 25, 2006	13566.105012
APPLICANT		GROUP ART UNIT / EXAMINER
Glynn Thomas Faircloth et al.		1654 / Maury Audet

## PENDING U.S. PATENT APPLICATIONS

EXAM. INITIAL	PATENT APPLICATION SERIAL NUMBER	FILING DATE	NAME OF FIRST-NAMED APPLICANT		
	10/182,881	06-3-2003	Fernando Albericio et al.		
	10/546,758	08-24-2005	Miguel Angel Izquierdo Delso		
	10/492,670	11-03-2004	Jose Jimeno		
	10/399,571	11-14-2003	Glynn Faircloth		
	10/642,006	08-14-2003	Paul Scheuer		
	10/570,734	03-06-2006	Fernando Albericio Palomera		
	11/587,177	10-19-2006	Andres Francesch Solloso		

EXAMINER	DATE CONSIDERED
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<b>FORM PTO-1498</b>			
<b>INFORMATION DISCLOSURE STATEMENT</b>			
<b>Applicant(s):</b>	<b>Glynn Thomas Faircloth et al.</b>		
<b>Serial No.:</b>	<b>10/531,533</b>		
<b>Filing Date:</b>	<b>April 25, 2006</b>		
<b>Group Art Unit:</b>	<b>1654</b>		
<b>Examiner:</b>	<b>Maury Audet</b>		
<b>Confirmation:</b>	<b>1346</b>		
<b>U.S. PATENT DOCUMENTS</b>			

<b>Examiner Initial</b>	<b>Patent No.</b>	<b>Issue Date</b>	<b>Name</b>	<b>Class</b>	<b>Subclass</b>	<b>Filing Date</b>
	US 6,011,010	Jan. 4, 2000	Gravalos et al.			
	US 5,849,704	Dec. 15, 1998	Sorensen et al.			
	US 4,959,175	Sep. 25, 1990	Yatzidis			
	US 5,932,189	Aug. 3, 1999	Dean et al.			
	US 2004/0052764	Mar. 18, 2004	Hildinger et al.			
	US 2003/0157685	Aug. 21, 2003	Zervos			
	US 2004/0214755	Oct. 28, 2004	Albericio et al.			
	US 2004/0067895	Apr. 8, 2004	Faircloth et al.			

<b>Examiner</b>	<b>Date Considered</b>
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

FORM PTG14495

## EXAMINER'S INFORMATION/PRE-CONSIDERATION STATEMENT

<b>Applicant (s):</b>	Glynn Thomas Faircloth et al.	<b>Serial No.:</b>	10/531,533
<b>Filing Date:</b>	April 25, 2006	<b>Group Art Unit:</b>	1654
<b>Examiner:</b>	Maury Audet	<b>Confirmation:</b>	1346

## EXAMINER'S INFORMATION/FOREIGN PATENT DOCUMENTS

<b>Examiner Initial</b>		<b>Patent Number</b>	<b>Pub. Date</b>	<b>Country</b>	<b>Translation</b>	
					<b>YES</b>	<b>NO</b>
	B1	WO 2004/075910	Sep. 10, 2004	WIPO		
	B2	WO 2005/023846	Mar. 17, 2005	WIPO		
	B3	WO 2005/103072	Nov. 3, 2005	WIPO		
	B4	WO 2001/58934	Aug. 16, 2001	WIPO		
	B5	WO 2002/36145	May 10, 2002	WIPO		
	B6	EP 0 838 221	Apr. 29, 1998	Europe		
	B7	WO 99/42125	Aug. 26, 1999	WIPO		
	B8	EP 0 610 078	Aug. 10, 1994	Europe		

Examiner \_\_\_\_\_ Date Considered \_\_\_\_\_

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

**FORM PTO-1449b**  
**INFORMATION DISCLOSURE STATEMENT**

<b>Applicant (s):</b>	Glynn Thomas Faircloth et al.	<b>Serial No.:</b>	10/531,533
<b>Filing Date:</b>	April 25, 2006	<b>Group Art Unit:</b>	1654
<b>Examiner:</b>	Maury Audet	<b>Confirmation:</b>	1346

**OTHER REFERENCES (Check each reference, File Date, Itemized Pages, Etc.)**

A1	G. M. Loudon, Organic Chemistry, Second Edition, Benjamin/Cummings Publishing Company, Inc., 1988, pages 924-926.
A2	Nuijen B et al., "Development of a lyophilized parenteral pharmaceutical formulation of the investigational polypeptide marine anticancer agent kahalalide F" Drug Development and Industrial Pharmacy, vol. 27, No. 8, pages 767-780, 2001.
A3	Faircloth G et al., "Preclinical development of kahalalide F, a new marine compound selected for clinical studies," Proceedings of the American Association for Cancer Research Annual, no. 41, March 2000 (2000-03), pages 600-601, XP001097542, 91 <sup>st</sup> Annual Meeting of the American Association for Cancer Research, San Francisco CA, USA; April 01-05, 2000, March, 2000 ISSN: 0197-016X
A4	Luber-Narod J et al., "Evaluation of the use of in vitro methodologies as tools for screening new compounds for potential in vivo toxicity." Toxicology In Vitro, vol. 15, no. 4-5, August 2001 (2001-08), pages 571-577, XP002225749, ISSN: 0887-2333, page 576, column 2, paragraph 2
A5	Brown Alan P et al., "Preclinical toxicity studies of kahalalide F, a new anticancer agent: single and multiple dosing regimens in the rat." Cancer Chemotherapy and Pharmacology. Germany Oct 2002, vol. 50, no. 4, October 2002 (2002-10), pages 333-340, XP002225750 ISSN: 0344-5704 abstract
A6	El Sayed, Khalid A. et al., "The Marine Environment: A Resource for Prototype Antimalarial Agents," Journal of Natural Toxins, Vol. 5, No. 2, pp. 261-285, 1996
A7	Garcia-Rocha, Mar et al., "The antitumoral compound Kahalalide F acts on cell lysosomes," Cancer Letters, vol. 99, no. 1, pp. 43-50, 1996
A8	Goetz, Gilles et al., "The Absolute Stereochemistry of Kahalalide F," Tetrahedron, vol. 55, pp. 7739-7746, 1999
A9	Goetz, Gilles et al., "Two Acyclic Kahalalides from the Sacoglossan Mollusk <i>Elysia rufescens</i> ," Journal of Natural Products, vol. 60, no. 6, p. 562-567, 1997
A10	Hamann, Mark T. et al., "Kahalalide F: A Bioactive Depsipeptide from the Sacoglossan Mollusk <i>Elysia rufescens</i> and the Green Alga <i>Bryopsis</i> sp.," Journal of the American Chemical Society, vol. 115, no. 13, pp. 5825-5826, 1993

Examiner

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**FORM PTO 1449b**  
**INFORMATION DISCLOSURE STATEMENT**

<b>Applicant (s):</b>	Glynn Thomas Faircloth et al.	<b>Serial No.:</b>	10/531,533
<b>Filing Date:</b>	April 25, 2006	<b>Group Art Unit:</b>	1654
<b>Examiner:</b>	Maury Audet	<b>Confirmation:</b>	1346

**OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)**

A11	Hamann, Mark T. et al., "Kahalalides: Bioactive Peptides from a Marine Mollusk <i>Elysia refuscens</i> and Its Algal Diet <i>Bryopsis</i> sp.," <i>The Journal of Organic Chemistry</i> , vol. 61, no. 19, pp. 6594-6600, 1996
A12	Hamann, Mark T. et al., "Kahalalides: Bioactive Peptides from a Marine Mollusk <i>Elysia refuscens</i> and Its Algal Diet <i>Bryopsis</i> sp.," <i>The Journal of Organic Chemistry</i> , vol. 63, no. 14, pp. 4856, 1998
A13	Horgen, F. David et al., "A New Depsipeptide from the Sacoglossan Mollusk <i>Elysia ornata</i> and the Green Alga <i>Bryopsis</i> Species," <i>Journal of Natural Products</i> , vol. 63, no. 1, pp. 152-154, 2000
A14	Kan, Yukiko et al., "Kahalalide K: A New Cyclic Depsipeptide from the Hawaiian Green Alga <i>Bryopsis</i> Species," <i>Journal of Natural Products</i> , vol. 62, no. 8, pp. 1169-1172, 1999
A15	Lopez-Macia, Angel et al., "Kahalalide B. Synthesis of a natural cyclodepsipeptide," <i>Tetrahedron Letters</i> , vol. 41, pp. 9765-9769, 2000
A16	Goodman & Gilman's, <i>The Pharmacological Basis of Therapeutics</i> , Ninth Edition, McGraw Hill, New York (1996), Section X, Chemotherapy of Neoplastic Diseases, pages 1225-1229.
A17	Hamann, Mark Todd, Ph.D., University of Hawaii (1992), "Biologically Active Constituents of Some Marine Invertebrates," UMI Dissertation Services, published October 1993.
A18	Merck Manual, 11 <sup>th</sup> ed., pp. 456-459, 761-763, and 1368-1371; published 1969.
A19	Lee Y S et al., "A convergent liquid-phase synthesis of salmon calcitonin" <i>Journal of Peptide Research</i> , Munksgaard International Publishers, Copenhagen DK, vol. 54, no. 5, October 1999 (1999-10), pages 328-335, XP000849313 ISSN: 1397-002X, figure 1
A20	Bonnard Isabelle et al., "Stereochemistry of kahalalide F," <i>Journal of Natural Products</i> . Nov 2003, vol. 66, no. 11, November 2003 (2003-11), pages 1466-1470, XP002337530 ISSN: 0163-3864 abstract
A21	Lopez-Macia et al., "Synthesis and Structure Determination of Kahalalide F." <i>J. Am. Chem. Soc.</i> , vol. 123, no. 46, pages 11398-11401, published on web Oct. 27, 2001.

Examiner

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